3189. Misbranding of Green Dragon liniment. U. S. v. 144 Bottles, etc. (F. D. C. No. 27877. Sample No. 48351–K.)

LIBEL FILED: September 26, 1949, Middle District of Pennsylvania; amended libel filed, February 1, 1950.

ALLEGED SHIPMENT: On or about September 10, 15, 19, and 20, 1949, from Cincinnati, Ohio, by the Green Dragon Medicine Co.

PRODUCT: 144 2-ounce bottles, and 6 cases, each containing 72 2-ounce bottles, of *Green Dragon liniment* at Lebanon, Pa. The libel was amended to cover goods actually seized, i. e., 48 bottles, and 20 cases, each containing 72 bottles.

RESULTS OF INVESTIGATION: This product was represented by Al Stofel, salesman for the distributor, the Green Dragon Medicine Co., during lectures delivered by him at the Allentown Fairgrounds on September 21, 1949, to be effective for stomach pains, rheumatic pains, arthritic pains, catarrh, and hay fever, and as a cure for any human pain in one to three minutes.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: June 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3190. Action to enjoin and restrain the interstate shipment of Acidofilac. U. S. v. Helen A. Walters (Radiance Products Co.). Consent decree granting injunction. (Inj. No. 220.)

COMPLAINT FILED: Between December 1, 1949, and January 26, 1950, Southern District of California, against Helen A. Walters, an individual, and as administratrix of the estate of William R. Walters, doing business under the name, Radiance Products Co., Los Angeles, California.

NATURE OF CHARGE: The defendant had been and was at the time of filing the complaint introducing and delivering for introduction into interstate commerce at Los Angeles, Calif., consignments of a drug designated as "Acidofilac," which was a culture of lactic acid-forming organisms and which was adulterated and misbranded in the following respects:

Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to possess a count of seven billion eight-hundred million viable *acidophilus* bacteria in each fluid ounce, whereas the article contained substantially less viable *acidophilus* bacteria in each fluid ounce.

Misbranding, Section 502 (a), the statements in the accompanying leaflet entitled "Acidofilac A vitalized pure aciduric bacterial milk food" represented and suggested that the use of the article would result in the prolongation of life; in outwitting middle age; and in keeping the system free from putrefactive bacteria and toxic poisons, resulting in the prolongation of the vigorous period of life; and that the article was useful in the treatment of certain stomach disorders, which statements were false and misleading since the article was not capable of fulfilling such promises of benefit. In addition,

* See also No. 3200.

the statement "A recent test made by the Truesdail Laboratories, Inc., of August 31, 1943, shows a count of seven billion eight hundred million viable acidophilus bacteria in each fluid ounce of bottle tested," contained in the accompanying leaflet, was misleading since the article contained only a small proportion of the number of viable *acidophilus* bacteria represented by such statement; and, the statement "Acidofilac A vitalized aciduric bacterial food A composite culture of selected strains of Lactobacilli-Acidophilus and Bulgaricus in skim milk. It is best to use before Oct. 11, 1949," appearing on the label of the article, was misleading since the statement represented and suggested that in the recommended dose stated on the label the article would supply prior to the date stated a therapeutically significant number of viable *Lactobacilli acidophilus* and *bulgaricus*, whereas it would not do so.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the adulterated and misbranded article.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of.

DISPOSITION: August 1, 1950. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from shipping in interstate commerce any *Acidofilac* or any like drug which was adulterated and misbranded as alleged in the complaint.

3191. Adulteration of Creme-A-Tone and adulteration and misbranding of Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and Estra-Beta capsules. U. S. v. Oxford Products, Inc. Plea of guilty. Fine of $1,300, plus costs. (F. D. C. No. 28112. Sample Nos. 353-K, 354-K, 358-K, 2252-K to 2254-K, incl., 3130-K, 21365-K, 21366-K, 30739-K, 30740-K, 42129-K, 43432-K, 43433-K.)

INFORMATION FILED: June 14, 1950, Northern District of Ohio, against Oxford Products, Inc., Cleveland, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of March 15, 1948, and March 14, 1949, from the State of Ohio into the States of Georgia, West Virginia, Virginia, Missouri, California, Illinois, and Michigan.

NATURE OF CHARGE: *Creme-A-Tone.* Adulteration, Section 501 (b), the article purported to be and was represented as aluminum hydroxide gel, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard; and the difference in the strength of the article from the standard was not plainly stated, or stated at all, on its label. The standard provides that aluminum hydroxide gel contains the equivalent of not less than 3.6 percent of aluminum oxide, and that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc. All shipments of the article contained the equivalent of less than 3.6 percent of aluminum oxide, and in one of the shipments the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc.

Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and *Estra-Beta capsules.* Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess. Misbranding, Section 502 (a), certain statements in the labeling